

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/526,697

Confirmation No. 9619

Applicant: Dudley et al.

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Commissioner for Patents
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DECLARATION UNDER 37 C.F.R. § 1.131

We, Mark E. Dudley, Steven A. Rosenberg, and John R. Wunderlich do hereby declare as follows:

1. We are the co-inventors of the pending claims in the above-referenced patent application.
2. We conceived of and reduced to practice the claimed invention in the United States before July 2, 2001, as evidenced by the following:
 - a. attached to this Declaration is a true and accurate copy of a report prepared by Mark E. Dudley. The report summarizes research performed involving the administration of non-myeloablative lymphodepleting chemotherapy followed by adoptive transfer of autologous T cells to melanoma patients. The autologous T-cells had been previously isolated and selected for highly avid recognition of an antigen of the melanoma by stimulation of the T-cells *in vitro* with the antigen of the melanoma. In patients A, B, E, and F, this *in vitro* stimulation of the T-cells was followed by one cycle of rapid

expansion using irradiated allogeneic feeder cells, OKT3 antibody, and IL-2. IL-2 was subsequently administered to the patients.

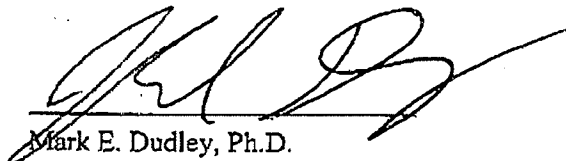
3. The treatment dates of Patients A-F which have been deleted from the report are prior to July 2, 2001.

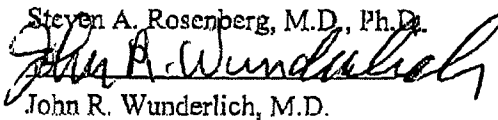
4. Each of us hereby declares that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/3/08

Date: _____

Date: 6/3/08


Mark E. Dudley, Ph.D.

Steven A. Rosenberg, M.D., Ph.D.

John R. Wunderlich, M.D.

ID#	Ref	Lvl	Patient	Treatment Characteristics			Current Clinical			Patient Characteristics			Other			DD	prior abt
				Days	Calls	Age	Rel. (cm)	Med. (cm)	Age (cm)	HLA	Seas. (cm)	Vas	BL	Code in vlog	Other		
A		Patient		33.0	33.0	A	PR (C)	NR	100	A02A11	AX RT TV	SK SU	2	lv	no clone		
B		Patient		35.0	35.0	6.6	PR (C)	NR	107	A01A02	SK SU	SK SU	2	lv	no clone		
C		Patient		39.8	39.8	6.6	NR	NR	437	A02A11	SK SU	SK SU	3	lv	no clone		
D		Patient		34.0	34.0	6.6	PR (C)	NR	576	A02A11	SK	SK	3	lv	no clone		
E		Patient		10.0	10.0	6.6	NR	NR	150	A02A03	NR SU TV LU	NR SU TV LU	3	lv	no clone		
F		Patient		36.3	36.3	A	PR (C)	NR	376	A02A11	NR SU TV LU	NR SU TV LU	3	lv	no clone		
G		Patient		12.6	12.6	6.6	NR	NR	404	A02A03	CE CL SU	CE CL SU	3	lv	no clone		
H		Patient		94.3	94.3	G	NR	NR	463	A02A30	SU	SU	3	lv	no clone		
I		Patient		93.7	93.7	6.6	PR (C)	NR	376	A02A03	SK SU	SK SU	3	lv	no clone		
J		Patient		109.0	109.0	M	PR (C)	NR	159	A02A0205	BN SK SU	BN SK SU	3	lv	no clone		
K		Patient		130.0	130.0	M	NR	NR	354	A02A11	BN SU CV LU PA	BN SU CV LU PA	3	lv	no clone		
L		Patient		170.0	170.0	M	NR	NR	376	A02A11	BN SU CV LU PA	BN SU CV LU PA	3	lv	no clone		
M		Patient		77.0	77.0	6.6	NR	NR	416	A02	BN SU CV LU PA	BN SU CV LU PA	3	lv	no clone		

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